3.0 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

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Date Prepared: October 26, 2012

Device Information:

Trade Name:	Pacific™ Plus
Common Name:	Percutaneous Transluminal Angioplasty Catheter
Regulation Name:	Percutaneous Catheter
Classification:	Class II
Classification Panel:	Peripheral
Regulation Number:	21 CFR 870.1250
Product Code:	LIT, DQY

Predicate Devices

- Pacific™ Xtreme PTA Balloon Dilatation Catheter (K103464 SE-12/22/2010)
- Amphirion™ DEEP 0.014" OTW PTA Balloon Catheter (K052791 SE-11/04/2005 and K083919 SE-03/13/2009)
- REEF HP™ 0.035" OTW PTA Balloon Dilatation Catheter (K092361 SE-10/29/2009)

Reference Device

- Amphirion™ Plus PTA Catheter (K121265 SE-05/22/2012)

Device Description

The Pacific Plus is an Over the Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) catheter consisting of a proximal hub, a coaxial dual lumen shaft, and a distal dilatation balloon. The lumen marked "WIRE" is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guide wire with a maximum outer diameter of 0.018 inches (0.46 mm). The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution. Two radiopaque marker bands are placed under the balloon segment of the catheter shaft to provide visual reference points for balloon positioning within the vessel.

The Pacific Plus catheter is compatible with guidewires with a maximum diameter of 0.018" (0.46 mm) and with 4F or 5F introducer sheaths depending on balloon size. The catheter is provided with a hydrophilic coating and is available in useable catheter lengths of 90, 130 and 180 cm.

Balloon sizes range from 2.0mm to 7.0mm in diameter, with balloon lengths from 20mm to 150mm. All balloons reach nominal diameter at 8atm (Nominal Pressure) and have rated burst pressure (RBP) of 22atm, 16atm, 14atm and 12atm depending on the balloon diameter and balloon length.

Indications for Use

The Pacific Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The indications for use for the Pacific Plus are equivalent and covered by the currently cleared predicate devices, Pacific Xtreme PTA Balloon Dilatation Catheter (hereinafter referred to as "Pacific Xtreme"), Amphirion DEEP PTA Balloon catheter (hereinafter referred to as "Amphirion DEEP") and REEF HP PTA Balloon Catheter (hereinafter referred to as "REEF HP").

Technological Characteristics

The Pacific Plus (hereinafter referred to also as "subject device") is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter. The overall design and the fundamental scientific technology (operating principle or mechanism of action) of the Pacific Plus device are

equivalent to the currently cleared predicate devices, Pacific Xtreme, Amphirion DEEP and REEF HP. Description of the modified device, Pacific Plus, is provided in the table below:

Characteristic	Modified Pacific Plus
Balloon Lengths (mm)	The subject device balloon lengths are within the Amphirion DEEP predicate device balloon length range.
Balloon Diameter (mm)	The subject device balloon diameters are within the Amphirion DEEP and REEF HP predicate devices balloon diameter range.
Balloon Material	The subject device with balloon diameter from 2.0mm to 4.0mm uses a balloon material type that is the same as the one used in the REEF HP predicate device. In addition the balloon material is supplied as compliant to USP Class VI. The Pacific Plus balloons with diameter from 5.0mm to 7.0mm use a material identical to the guidewire tube component of the Pacific Xtreme predicate device. Biocompatibility evaluation and comparative, design verification and shelf life testing have been performed on the subject device in order to support with objective evidence its safety and effectiveness and the results met the required specifications.
Catheter Useable Length (cm)	The Pacific Plus 90cm and 130cm usable lengths are within the Pacific Xtreme predicate device's range, while the longer catheter useable length of 180cm was designed for the subject device increasing the shaft length by 30cm compared to Amphirion DEEP without changing the fundamental scientific technology. This longer catheter useable length was added to the subject catheter usable length size matrix in order to expand the size offerings and it is driven by the need to provide the physicians with a more comprehensive size mix. There are no changes to the technical features of the usable length design and the 180cm shaft length is made of identical materials and manufacturing processes as the other sizes. Proper design verification, shelf life and comparative testing has been performed on the subject device in order to support with objective evidence its safety and effectiveness and all the results have met the requested specifications.
Catheter Shaft Diameter	The shaft diameter is within the range of the Pacific Xtreme shaft diameters.
Catheter Shaft Material	The Pacific Plus catheter shaft material is identical to the material used on the Amphirion DEEP predicate device.
Catheter Coating	The coating has the same base and function as the coating of the Amphirion DEEP and Pacific Xtreme predicate devices; three reagents have been changed in the formula in comparison to the predicate devices with no new risks. Biological evaluation and comparative, design verification and shelf life testing have been performed on the subject device in order to support with objective evidence its safety and effectiveness and the results met the required specifications.
Guidewire Compatibility	The subject device guidewire compatibility is within the Amphirion DEEP and Pacific Xtreme predicate devices guidewire compatibility range.
Guidewire Tube Material	The subject device guidewire tube material is the same as the Pacific Xtreme predicate device guidewire tube material.

Characteristic	Modified Pacific Plus
Introducer Sheath Compatibility	The subject device introducer sheath compatibility is the same as the Pacific Xtreme predicate device introducer sheath compatibility.
Nominal Pressure (atm)	The nominal pressure (8atm) is within the range of the REEF HP and Pacific Xtreme predicate devices nominal pressure.
Rated Burst Pressure (atm)	The subject device has a Rated Burst Pressure (RBP) of 22,16,14 and 12 atm depending on balloon diameters. These RBPs are within the range of the REEF HP and Pacific Xtreme predicate devices RBP.

Summary of Bench Testing

The Pacific Plus was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications. The bench testing plan was developed with the consideration of the recommendations outlined in the applicable FDA guidance documents, ISO and ASTM standards. Testing performed on the Pacific Plus device included the following:

- Dimensional verification
- Balloon preparation, deployment and retraction
- Balloon rated burst pressure (RBP)
- Balloon fatigue (repeated balloon inflations)
- Balloon Compliance
- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Flexibility and Kink test
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate evaluation
- Guide wire compatibility
- Introducer sheath compatibility
- Coating lubricity

All of the pre-determined acceptance criteria were met and results passed.

Summary of Biocompatibility Testing

The Pacific Plus is an externally communicating device, which contacts circulating blood for the limited contact duration (<24hours).

Biocompatibility testing was conducted on the finished Pacific Plus in accordance with the principles of the ANSI/AAMI/ISO 10993-1:2009 *Biological evaluation of medical devices --*

Part 1: Evaluation and testing within a risk management process as specified in the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* and in accordance with FDA 21 CFR Part 58: *Good Laboratory Practice for Non clinical Laboratory Studies*, and FDA guidance: *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (Sept 2010).*

The biocompatibility testing performed for the Pacific Plus device included the following:

- ISO L929 MEM Elution Test
- ISO Kligman Maximization Test
- ISO Intracutaneous Injection Test
- ISO Systemic Injection Test
- ISO Material Mediated Rabbit Pyrogen Test
- ISO *Salmonella Typhimurium and Escherichia Coli* Reverse Mutation Assay (AMES Test)
- ASTM Direct and Indirect Contact – Hemolysis – Rabbit Blood
- ISO Complement Activation Assay (Indirect Contact)
- ISO In-vivo Dog Thromboresistance

All of the pre-determined acceptance criteria were met and results passed.

Assessment of non-clinical performance data for equivalence

Bench and biocompatibility testing of the Pacific Plus were performed in accordance with the relevant FDA guidance, ISO and ASTM standards. Results from these non-clinical testing demonstrates that the Pacific Plus met the pre-determined acceptance criteria and performs comparably to the predicate devices. No new type of safety or effectiveness issues were observed during the testing.

Conclusion

Based on the considerations above, Medtronic believes that the Pacific Plus is substantially equivalent to the predicate devices Pacific Xtreme, Amphirion DEEP and REEF HP in terms of indications for use, design, material, fundamental scientific technology (operating principle or mechanism of action) and performance characteristics, therefore it is suitable for the Traditional 510(k) process.

Results from the non-clinical performance testing demonstrate that the Pacific Plus is substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 29 2013

Medtronic Vascular
c/o Ms. Diana Johnson, Regulatory Affairs Director
3576 Unocal Place
Santa Rosa, CA 95403

Re: K123358
Trade/Device Name: Pacific™ Plus PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: October 26, 2012
Received: October 31, 2012

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K123358

Device Name: Pacific™ Plus

Indications For Use:

The Pacific™ Plus PTA catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123358